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Docket No. AZ0017-USA-NP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Jao et al.

Serial No. : 10/628,970

Art Unit: 1732

Filed : July 28, 2003

Examiner:

For : FORMULATIONS AND DOSAGE FORMS FOR CONTROLLED  
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March 29, 2005

(Date of Deposit)

Mary A. Appollina, Reg. No. 34, 087

(Name of applicant, assignee, or Registered Representative)

/Mary A. Appollina/

(Signature)

March 29, 2005

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Washington, D.C. 20231

FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure  
Statement mailed on February 20, 2004.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37  
C.F.R. §§1.97-1.98, information relating to the above-  
identified application is hereby disclosed. Inclusion of  
information in this statement is not to be construed as an  
admission that this information is material as that term is  
defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the  
patentability of the claimed invention over any of the  
information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a) (2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

Copies of the references listed on the search report(s) are included except for those previously cited in an IDS mailed

☒ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

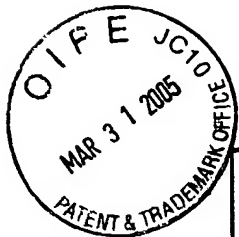
Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/AZ0017/MAA. This form is submitted in triplicate.

Respectfully submitted,

/Mary A. Appollina/  
Mary A. Appollina  
Reg. No. 34,087  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-3742  
DATED: March 29, 2005





PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 1 of 3

|                        |               |
|------------------------|---------------|
| Application Number     | 10/628,970    |
| Filing Date            | 07/28/2003    |
| First Named Inventor   | Jao et al.    |
| Group Art Unit         | 1732          |
| Examiner Name          |               |
| Attorney Docket Number | AZ0017-USA-NP |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | U.S. Patent Document |                                      | Name of Patentee or Applicant<br>of Cited Document | Date of Publication<br>of Cited Document<br>mm-dd-yyyy | Pages, Columns, Lines,<br>where relevant passages or<br>relevant figures appear |
|----------------------|--------------------------|----------------------|--------------------------------------|--|--|---|
|                      |                          | Number               | Kind Code <sup>2</sup><br>(if known) |  |  |   |
|                      |                          | 6,248,363            |                                      | Patel et al.                                       | 06-19-2001   |   |
|                      |                          | 6,569,463            |                                      | Patel et al.                                       | 05-27-2003   |   |
|                      |                          | 2001/0012847         | A1                                   | Lam et al.   | 09-09-2001   |   |
|                      |                          | 6,294,192            |                                      | Patel et al.                                       | 09-25-2001   |   |
|                      |                          | 5,906,832            |                                      | Jao et al.   | 05-25-1999   |   |
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|                      |                          | 5,262,171            |                                      | Login et al.                                       | 11-16-1993   |   |
|                      |                          | 2002/0044960         | A1                                   | Cherukuri  | 04-18-2002   |   |
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|                      |                          | 2002/0127196         | A1                                   | Avila et al.                                       | 09-12-2002   |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. <sup>1</sup> | Foreign Patent Document |                     |                       | Name of Patentee or<br>Applicant of Cited Document | Date of Publication<br>of Cited Document<br>mm-dd-yyyy | Pages, Columns, Lines,<br>where relevant<br>passages or relevant<br>figures appear | T <sup>6</sup> |
|----------------------|--------------------------|-------------------------|---------------------|-----------------------|--|--|--|----------------|
|                      |                          | Office <sup>3</sup>     | Number <sup>4</sup> | KindCode <sup>5</sup> |  |  |  |                |
|                      |                          | WO                      | 01/37808            |                       | Patel et al.                                       | 05-31-2001   |  |                |
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|                      |                          | WO                      | 98/23263            |                       | Homel et al.                                       | 06-04-1998   |  |                |
|                      |                          | WO                      | 00/00179            |                       | Beom et al.  | 01-06-2000   |  |                |
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|                      |                          | WO                      | 04/00244<br>7       | A1                    | Edgren et al.                                      | 01-08-2004   |  |                |

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
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Sheet 2 of 3

|                               |               |
|-------------------------------|---------------|
| <b>Application Number</b>     | 10/628,970    |
| <b>Filing Date</b>            | 07/28/2003    |
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|                      |                          | Number               | Kind Code <sup>2</sup><br>(if known) |  |  |   |
|                      |                          | 2003/0185882         | A1                                   | Vergez et al.                                      | 10-02-2003   |   |
|                      |                          | 2003/0228358         | A1                                   | Perlman et al.                                     | 12-11-2003   |   |
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|                      |                          | 2002/0022245         | A1                                   | Hebebrand et al.                                   | 02-21-2002   |   |
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|                      |                          | 2005/0053653         | A1                                   | Kidane et al.                                      | 03-10-2005   |   |

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|                      |                          | Office <sup>3</sup>     | Number <sup>4</sup> | KindCode <sup>5</sup> |  |   |  |                |
|                      |                          | WO                      | 02/44276            | A2                    | Avila et al.                                       | 06-06-2002  |  |                |
|                      |                          | WO                      | 03/002151           | A1                    | Massironi  | 01-09-2003  |  |                |
|                      |                          | WO                      | 03/004009           | A1                    | Matharu et al.                                     | 01-16-2003  |  |                |
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|                      |                          | WO                      | 03/063833           | A1                    | Perlman et al.                                     | 08-07-2003  |  |                |

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Sheet 3 of 3

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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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| <b>SUBMISSION UNDER MPEP 609 D</b><br><br><b>Page 1 of 1</b> | <b>Application Number</b>     | 10/628,970    |
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|                      |                          |  | Number               | Kind Code <sup>2</sup><br>(if known) |   |
|                      |                          | D. Edgren et al.                                   | USSN 10/606575       |                                      |   |
|                      |                          | I. Reyes et al.                                    | USSN 10/910,040      |                                      |   |
|                      |                          | N. Yam et al.                                      | USSN 10/920,934      |                                      |   |
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|                      |                          | D. Edgren et al.                                   | USSN 11/024,330      |                                      |   |
|                      |                          | D. Edgren et al.                                   | USSN 11/024,378      |                                      |   |
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|                      |                          |  | Office <sup>3</sup>     | Number <sup>4</sup> | KindCode <sup>5</sup> |  |                |
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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>'s<br>Initials* | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate),<br>title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s),<br>volume-issue number(s), publisher, city and/or country where published | T <sup>2</sup> |
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| Examiner<br>Signature |  | Date<br>Considered |  |
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